Remarks

Attorney for Applicants gratefully acknowledges the Examiner's clarification of the species restriction in a phone conversation on March 30.

Claims 1-44 are pending in the application, and are subject to a restriction requirement. The Examiner has restricted the present claims into six groups. The Examiner has additionally restricted the claims to a single peptide and has further restricted the elected single peptide to a sequence that specifies either D or L amino acids.

Applicants elect the claims of Group II (claims 5-8 and 10-30) for immediate prosecution. Applicants note the potential for rejoinder of Groups III-VI with Group II. Applicants elect, ***with traverse***, the peptide sequence recited in claim 6 (SEQ ID NO: 2). Applicants elect, ***with traverse***, the L-configuration for the amino acids composing the elected sequence.

Traverse of the Species Restriction

Applicants traverse the portion of the restriction requiring election of a single peptide, and requiring specifying whether the elected sequence is composed of D- or L- amino acids.

The Examiner alleges at page 3 in the Detailed Action that the claims "encompass a large number of peptides, the different permutations that can be made from the claims." The Examiner further asserts that the requirement to elect a **single** peptide, and to specify if the elected sequence consists of D or L amino acids, is not to be construed as a species election requirement, but rather a restriction requirement. The Examiner states that each of the claimed peptides "has a different structure and attendant immunological and chemical properties" which would require separate searches for each peptide. Applicants respectfully disagree.

According to MPEP 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

> (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
>
> (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

Here, the Examiner cannot show that the peptide sequences defined in the claims of Group II represent independent or distinct inventions, or that there is a serious burden on searching and examining all of the defined peptides of Group II in one application.

A. The peptide sequences are not *independent* inventions

The term "independent" is defined in MPEP § 802.01 as meaning "that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process."

Claims 5-8 and 10-30 (designated by the Examiner as Group II) are directed to a defined group of peptides that constitute related subject matter. The claimed peptides are not "unconnected in design, operation, or effect." Each peptide of Group II is designed to achieve the same desired effect, *i.e.*, blocking interaction of the HIV-1 virus with the CXCR4 coreceptor. Each claimed peptide of Group II comprises a chemical structure that is designed in the same way, *i.e.* each is derived from structure of the N-terminus of vMIP-II. All of the peptides defined in the claims of Group II are embraced by a core chemical formula:

$$X\text{-}R_1\text{-}R_2\text{-}R_3\text{-}R_4\text{-}R_5\text{-}R_6\text{-}R_7\text{-}R_8\text{-}R_9\text{-}R_{10}\text{-}R_{11}\text{-}R_{12}\text{-}R_{13}\text{-}R_{14}\text{-}R_{15}\text{-}R_{16}\text{-}R_{17}\text{-}R_{18}\text{-}R_{19}\text{-}R_{20}\text{-}\ R_{21}\text{-}Y$$

wherein elements of R_1 to R_{21}, X, and Y are specifically defined in the claim. Each of R_1 to R_{21} is conservatively defined as representing from two to four specific amino acids. For example, for R_2, R_3 and R_{14}, the selection is merely between the amino acid side chains of –H and $-CH_3$ (glycine and alanine, respectively). Peptide sequences representative of Group II are exemplified in the specification as filed. The representative peptide sequences in Applicants' specification include sequences containing L-amino acids (V1, page 5, below paragraph 0144), D-amino acids (DV1, page 6, line 17) and combinations of L- and D-amino acids (V1-DCL and V1-LCD, page 6, lines 20 and 22, respectively).

All of the presently claimed peptide compounds of Group II are thus connected in design, operation, and effect. Applicants respectfully submit that the compounds defined in claims 5-8 and 10-30 are no more and no less than a set of organic molecules defined by a common generic formulae characterized by defined variables. Clearly, the claimed peptide sequences are not independent inventions.

B. The peptide sequences are not *distinct* inventions

Since the claimed peptides of Group II are not independent, restriction is only proper if they are distinct. MPEP § 808.02 states that "[I]nventions are distinct only if they are 1) classified separately, 2) have acquired separate status in the art when classified together, or 3) require a

different field of search, *i.e.*, it is necessary to search for one invention in places where no pertinent art exists for the others.

The Examiner has classified all Group II claims under class 930, subclass 21. Thus, the peptides recited in the Group II claims are not classified separately under § 808.02(A). Likewise, since the peptides defined in the claims of Group II are classified under the same class/subclass, it would be unnecessary to "search for one peptide in places where no pertinent art exists for the others." Moreover, the Examiner has not alleged that the different peptides defined in the claims of Group II have "acquired a separate status in the art."

The Examiner has provided no reasoning why the peptide sequences defined in the claims of Group II are distinct, but has merely stated a conclusion that she considers the inventions to be distinct. Such a conclusory statement is inadequate to establish that the peptides within Group II represent distinct inventions. The present restriction requirement is therefore improper, and should be withdrawn.

C. *There is no Serious Burden in Searching Conjugates of the Formula $(R\text{-}X)_n$-Peptide*

Even assuming arguendo that peptides defined by the generic formulae (for example the formula:

$$X\text{-}R_1\text{-}R_2\text{-}R_3\text{-}R_4\text{-}R_5\text{-}R_6\text{-}R_7\text{-}R_8\text{-}R_9\text{-}R_{10}\text{-}R_{11}\text{-}R_{12}\text{-}R_{13}\text{-}R_{14}\text{-}R_{15}\text{-}R_{16}\text{-}R_{17}\text{-}R_{18}\text{-}R_{19}\text{-}R_{20}\text{-}\ R_{21}\text{-}Y$$

of claim 5 represent independent or distinct inventions, restriction is not proper because there is no serious burden on the Examiner in searching the peptides as claimed in Group II.

According to MPEP § 803 (emphasis added), "a serious burden . . . may be prima facie shown if the examiner shows *by appropriate explanation* either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02." The Examiner has given no explanation regarding any of the criteria of MPEP § 803 in support of a contention that searching the peptides defined by the claims of Group II poses a serious burden.

As discussed above, there can be no serious burden in searching the peptides of Group II together, because the compounds are defined by a common formula, are used for the same purpose, and are classified in the same class and subclass.

Conclusion

For the above reasons, Applicants respectfully request withdrawal of the restriction requirement as to election of a single peptide sequence and the specification within the elected single peptide of a sequence comprising either D or L amino acids.

Applicants believe this response to be fully responsive to the outstanding Restriction Requirement and request prosecution on the merits.

Respectfully submitted,

ZIWEI HUANG et al.

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DANIEL A. MONACO
Registration No. 30,480
DRINKER, BIDDLE & REATH, LLP.
One Logan Square, 18th and Cherry Streets
Philadelphia, PA 19103
Tel. (215) 988-3312
Fax (215) 988-2757
Attorney for Applicants